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**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/483,543 01/14/00 MUIR

T 600-1-259

000110 HM22/1005  
DANN DORFMAN HERRELL & SKILLMAN  
SUITE 720  
1601 MARKET STREET  
PHILADELPHIA PA 19103-2307

EXAMINER

WEBER, J

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

10/05/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

**Office Action Summary**

Application No.

09/483,543

Applicant(s)

MUIR ET AL.

Examiner

Jon P. Weber, Ph.D.

Art Unit

1651

-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 15-32 and 34-49 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 50 is/are allowed.
- 6) ☒ Claim(s) 1-14 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Notice to Comply*.

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***Status of the Claims***

Claims 1-50 have been presented for examination.

***Election/Restrictions***

Claims 15-32 and 34-49 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention made **without** traverse. Claims 1-14, 33 and 50 remain to be considered on the merits.

***Specification***

The disclosure is objected to because of the following informalities: At page 31, line 20 and page 37, line 3, "the -" is recited but it is unclear what this means.

This application contains additional sequence disclosures at page 28, line 6, page 42, line 22 and page 43, line 8 that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with one or more of the requirements of 37 C.F.R. § 1.821 through 1.825 for one or more of the reasons set forth on the attached form "Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequences And/Or Amino Acid Sequence Disclosures". Wherein attention is directed to paragraph(s) §1.82(c) and (e). Although an examination of this application on the merits can proceed without prior compliance, compliance with the Sequence Rules is required for the response to this Office action to be complete.

Appropriate correction is required.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Applicant is advised that should claim 13 be found allowable, claim 33 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "or a fragment thereof" in line 5. There is insufficient antecedent basis for this limitation in the claim. Further, the expression is vague and indefinite because the metes and bounds of the term are unknown.

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Claim 7 recites "recombinant" which is vague and indefinite because it is not clear if the peptide itself is recombined into a different structure or it has been prepared by recombinant means.

Claim 8 recites the limitation "N-terminal cysteine and C-Terminal "thioester" in lines 1-2. There is insufficient antecedent basis for this limitation in the basis claim that does not have these group at the termini. In the disclosure, the first fluorophore on a linking peptide is attached via the cysteine, but not on the cysteine, and the "thioester group is used to couple with a peptide comprising the second fluorophore. This claim appears to be directed to an intermediate peptide in the synthesis.

Claim 10 recites "BODIPY fluorescein" for both the acceptor and donor. It is thought that one member should be "BODIPY FL fluorescein".

Claim 14 recites "a third sensor" which is vague and indefinite because the location and means of attachment of the third sensor to the peptide are unclear.

### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-7 and 9-12 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Garman (US 6,291,201) or under 35 U.S.C. 102(b) as being anticipated by one of Marshall et al. (US 5,011,910), <sup>Protein</sup> Kraft et al. (EP 428,000), <sup>Protein</sup> Tsien et al. (WO 9200388), <sup>Protein</sup> Meldal et al. (WO 9116336), <sup>Wang Protein</sup> Maggiora et al. (1992), <sup>Protein</sup> Geoghegan et al. (1993), <sup>Protein</sup> Carmel et al. (1973), <sup>Protein</sup> Wang et al. (1990), <sup>Protein</sup> Ashcom et al. (1989), <sup>Protein</sup> Garcia-Echeverria et al. (1992), <sup>Protein</sup> Pennington et al. (1994), <sup>Protein</sup> Matayoshi et al. (1990), <sup>Protein</sup> Dobryszewski et al. (1988), <sup>Protein</sup> Latt et al. (1972), <sup>Protein</sup> Carmel et al. (1978), <sup>Protein</sup> Yaron et al. (1979), <sup>Protein</sup> Boigegrain et al. (1990), <sup>Protein</sup> Oliveira et al. (1992), <sup>Still good</sup> Miki et al. (1993), <sup>Protein</sup> Wang et al. (1994), or Wolfman et al. (1977).

Each of Garman (US 6,291,201), Marshall et al. (US 5,011,910), Kraft et al. (EP 428,000), Tsien et al. (WO 9200388), Meldal et al. (WO 9116336), Maggiora et al. (1992), Geoghegan et al. (1993), Carmel et al. (1973), Wang et al. (1990), Ashcom et al. (1989), Garcia-Echeverria et al. (1992), Pennington et al. (1994), Matayoshi et al. (1990), Dobryszewski et al. (1988), Latt et al. (1972), Carmel et al. (1978), Yaron et al. (1979), Boigegrain et al. (1990), Oliveira et al. (1992), Miki et al. (1993), Wang et al. (1994), and Wolfman et al. (1977) discloses fluorescence resonance energy transfer peptides or polypeptides having acceptors and donors

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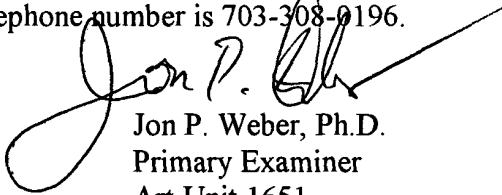
either at opposite ends or distributed within the sequence. The peptides are variously used as sensors of catalytic activity, conformation changes within the protein, or distance measurements within the peptide or protein. In most cases, internal quenching is relieved and accompanied by a concomitant increase in fluorescence when the detected activity occurs. A wide variety of acceptor/donor pairs are used. See also Haugland (1992) for a sampling of well-known fluorophores used as probes and acceptor/donor pairs.

Claim 50 is allowed. None of the cited art discloses or reasonably suggests attaching fluorescent acceptor/donor pairs to this peptide, or even this complete sequence of peptide. The crk peptide itself is known, but not with the added residues on the amino and carboxyl termini.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P. Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P. Weber, Ph.D.  
Primary Examiner  
Art Unit 1651

JPW

October 1, 2001

<b>Notice to Comply</b>	Applicati n N .	Applicant(s)	
	09/483,543	MUIR ET AL.	
	Examiner	Art Unit	
	Jon P. Weber, Ph.D.	1651	

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: Additional sequences needed.

**Applicant Must Provide:**

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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